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**PATENT APPLICATION**

**THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of

Docket No: Q96496

Yusuke ISHII, et al.

Appln. No.: 10/588,857

Group Art Unit: 1751

Confirmation No.: 2021

Examiner: Not yet assigned

Filed: August 9, 2006

For: SOLIFENACIN SUCCINATE-CONTAINING COMPOSITION

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §§ 1.97 and 1.98**

**MAIL STOP AMENDMENT**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

One copy of each of the listed documents is submitted herewith, except for the following: U.S. patents and/or U.S. patent publications; and co-pending non-provisional U.S. applications filed after June 30, 2003.

The present Information Disclosure Statement is being filed: (1) No later than three months from the application's filing date; (2) Before the mailing date of the first Office Action on the merits (whichever is later); or (3) Before the mailing date of the first Office Action after

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filin a request for continued examination (RCE) under §1.114, and therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

In compliance with the concise explanation requirement under 37 C.F.R. § 1.98(a)(3) for foreign language documents, Applicant encloses herewith a copy of an International Search Report listing JP-A-2002-104968 (along with an English translation) and WO 03/006019 A1 (which corresponds to US-2004-0138252) indicating the degree of relevance found by the foreign patent office. Further, EP 0 801 067 A1 is in English, corresponds to U.S. Patent 6,017,927 and is cited and discussed in the background section of the specification.

Also, the article entitled "Controlling Particle Size and Improving Fluidity of YM905 with Investigation of Crystallized Conditions" is accompanied by an English translation, and is also cited and discussed in the Background section of the specification. The remaining cited articles, in English, are cited and discussed in the Background section of the specification.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

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The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



Mark Boland  
Registration No. 32,197

SUGHRUE MION, PLLC  
Telephone: (202) 293-7060  
Facsimile: (202) 293-7860

WASHINGTON DC SUGHRUE/265550

**65565**

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Date: May 8, 2007

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~~INFORMATION DISCLOSURE STATEMENT BY APPLICANT~~

(use as many sheets as necessary)

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Complete if Known

Application Number	10/588,857
Confirmation Number	2021
Filing Date	August 9, 2006
First Named Inventor	Yusuke ISHII
Art Unit	1751
Examiner Name	Not yet assigned

Attorney Docket Number

Q96496

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number	Kind Code <sup>2</sup> (if known)		
		US 2004/0138252	A1	07/15/2004	Ikeda et al.
		US 6,017,927	A	01/25/2000	Takeuchi et al.
		US			

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			
		JP	2002-104968	A	10/04/2002		Yes
		WO	03/006019	A1	01/23/2003		With English abstract
		EP	0 801 067	A1	10/15/1997		English

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation <sup>6</sup>
		Shuichi NAKAGAWA et al., "Controlling Particle Size and Improving Fluidity of YM905 with Investigation of Crystallized Conditions" (2002) Japan Process Chemistry Association , pp. 85-86	Yes
		Christine E. HEADING, "Current Opinion in Central & Peripheral Nervous System Investigational Drugs" (2000), Vol. 2, No. 3, pp. 321-325	English
		"Treatment of Urinary Incontinence Muscarinic M <sub>3</sub> Antagonist" (1999), PROUS SCIENCE, Vol. 24, No. 8, pp. 871-874	English
		Ken Ikeda et al., "M <sub>3</sub> receptor antagonism by the novel antimuscarinic agent solifenacina in the urinary bladder and salivary gland" (2002) Naunyn-Schmiedeberg's Arch Pharmacol, Vol. 366, No. 2, pp. 97-103	English
		Seiji KOBAYASHI et al., "Effects of YM905, a Novel Muscarinic M <sub>3</sub> -Receptor Antagonist, on Experimental Models of Bowel Dysfunction In Vivo" (2001) Jpn. J. Pharmacol., Vol. 86, No. 3, pp. 281-288	English
		International Search Report dated March 2, 2005	

Examiner Signature

Date Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov), MPEP 901.04 or follow the hyperlink from the title of the document to the intranet. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to indicate here if English language Translation is attached.